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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/590,936	08/28/2006	Rita De Santis	725.1051	2737

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EXAMINER	
HADDAD, MAHER M	

ART UNIT	PAPER NUMBER
1644	

NOTIFICATION DATE	DELIVERY MODE
09/28/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

info@lmiplaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/590,936	DE SANTIS ET AL.	
	Examiner	Art Unit	
	Maher M. Haddad	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment, filed on 08/28/2006, is acknowledged.

Claims 1-34 *are pending and being acted upon presently*

2. Applicant is reminded that "use" claims are non-statutory and are not appropriate for US practice (see MPEP 2173.05(q)).

For examination purposes "use" claims are interpreted as a method of the first recited "use".

3. It is noted that claimed SEQ ID NO:1 is a nucleic acid sequence not an amino acid sequence as contemplated in claim 1. SEQ ID NO: 2 is an amino acid sequence.

Election/Restrictions

4. Restriction is required under 35 U.S.C. 121 and 372.
This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

5. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-8, 12, 15-16, 21-28, and 33, drawn to an anti-human tenascin monocloncal antibody, preferably murine, whose light and heavy chain variable region sequences are SEQ ID 1 and SEQ ID 2, respectively, its proteolytic fragments capable of binding to an antigenic epitope within the A(I.4)-D region of human tenascin, its recombinant derivatives, its conjugates and similar functional analogues capable of binding to an antigenic epitope within the A(1-4)-D region of human tenascin, fragments, recombinant derivatives, derivatives, bioltinylated, hybridoma, pharmaceutical compositions and kits thereof and a process for preparation, .

Group II, claims 9-11 and 13, drawn to a DNA encoding the anti-human tenascin monoclonal antibody comprising SEQ ID NOs: 1 and 2, vectors and host cells.

Group III, claim 14, drawn to specific CDRs (Complementary Determining Regions) of the antibody according to claim 1 and proteins containing said CDRs.

Group IV, claims 17-20 and 29, drawn to a process for the preparation of a pharmaceutical product useful for the treatment or diagnosis of a disease characterized by expression of tenascin comprising the anti-human tenascin monoclonal antibody comprising SEQ ID NOs: 1 and 2.

Group V, claim 30, drawn to container, preferably in the form of a vial, suitable for injection, containing an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues comprising the anti-human tenascin monoclonal antibody comprising SEQ ID NOs: 1 and 2, optionally biotinylated, and/or radiolabelled or its fragments, optionally biotinylated, or its biotinylated derivatives.

Group VI, claims 31-32, drawn to a tumour imaging method including the administration of an antibody or its proteolytic fragments or its recombinant derivatives or its conjugates or analogues comprising the anti-human tenascin monoclonal antibody comprising SEQ ID NOs: 1 and 2, optionally bio-tinylated, or its fragments, optionally biotinylated, or its biotinylated derivatives to a person suffering from or suspected of suffering from a tumour, and the detection of said tumour.

Group VII, claim 34, drawn to a method of determining circulating tenascin levels, particularly levels of the isoforms containing the $A_{(1-4)}$-D region with the antibody combination comprising the anti-human tenascin monoclonal antibody comprising SEQ ID NOs: 1 and 2, and a second antibody binds to a second antigenic epitope.

6. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of De Santis et al (Cancer Biotherapy & Radiopharmaceuticals. August 2004, 19(4): 512-541) (see entire abstract).

De Santis et al developed anti-tenascin monoclonal antibody ST2485, directed towards an epitope within the alternatively spliced A-D region of the fibronectin-like repeats, absent in the small tenascin isoform 220 kda. (see Abstract # 26). It is noted that ST2485 comprises claimed SEQ ID NOs: 1 and 2, as is evidenced by the specification under Figures 17 and 18.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

Species Election

6. Irrespective of whichever group applicant may elect, applicant is further required under 35 US 121 (1) to elect a single disclosed species to which claims would be restricted if no generic

claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

If Group I is elected, applicant is required to elect an ultimate component of each vials, vials-1-5, such as the one recited in claim 22-26. In addition, Applicant is required to elect a particular biotin DOTA such as the one listed in claim 24. These are distinct species because their structures and modes of action are different which, in turn, address different therapeutic endpoints.

7. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

There is an examination and search burden for these patentably distinct species due to their mutually exclusive characteristics. The species require a different field of search (e.g., searching different classes/subclasses or electronic resources, or employing different search queries); and/or the prior art applicable to one species would not likely be applicable to another species; and/or the species are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected species,** including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

The election of the species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the election of species requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected species.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the species unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other species.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.

8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

September 23, 2010

/Maher M. Haddad/
Primary Patent Examiner
Technology Center 1600